

## **REMARKS**

### **35 USC § 112, First Paragraph – Written Description**

The Examiner rejected Claims 1-27 under 35 USC § 112, First Paragraph, as allegedly failing to comply with the written description requirement.

Applicants disagree with the Examiner and respectfully submit that the instant specification satisfies the written description requirement because it would be clear to one skilled in the art that Applicants possessed the claimed subject matter at the time of filing the instant application.

Rejection of Claims 2-10 and 13-20 is moot in view of cancellation of these Claims.

As pointed out by the Examiner at page 3, first paragraph, of the instant Office Action, the specification (pages 18-42) satisfies the written description requirement for a method in which a plant is provided by gene transfer with a gene expression inducing system that comprises (1) a first genetic construct comprising a gene placed under the control of a sequence of SEQ ID NO: 3 that functions as an operator, and (2) a second genetic construct that functions as a repressor of SEQ ID NO: 2, wherein the actinomycete autogenous regulatory factor virginiae butanolide acts to induce the expression of the gene placed under control of the operator sequence. Furthermore, the Examiner also stated that the specification further describes the first genetic construct as comprising SEQ ID NO: 3 that functions as an operator when one, two, or three copies of SEQ ID NO: 3 are located 3' downstream and/or 5' upstream of the TATA box of the Cauliflower mosaic virus 35S promoter in the arrangement set forth in SEQ ID NOS: 4-7.

Applicants amended Claim 1 to include subject matter that was pointed out by the Examiner to satisfy the written description requirement. In view of the amendment, the rejection of Claims 1, 11, 12, 21-27 is moot. However, Applicants reserve the right to pursue the rejected claims in future prosecution.

Applicants respectfully submit that Claims 1, 11, 12, 21-27 satisfy the written description requirement of 35 U.S.C. § 112, First Paragraph, and therefore, Applicants respectfully request the rejection be withdrawn.

### **35 USC § 112, First Paragraph - Enablement**

Claims 1-27 were rejected under 35 USC §112, First Paragraph, for allegedly not being enabled by the specification.

Applicants disagree.

In the Office Action at page 4, last paragraph, the Examiner pointed out that the specification is enabling for a gene expression inducing system comprising a gene placed under the control of an operator, wherein a nucleotide sequence of the operator comprises a region comprising a nucleotide sequence of SEQ ID NO: 3, and the operator is connected to at least one site 3' downstream or 5' upstream of TATA box of a Cauliflower mosaic virus 35S promoter in arrangement as set forth in SEQ ID NOS: 4-7; and a repressor, wherein a gene coding for the repressor comprises a nucleotide sequence of SEQ ID NO: 1, or comprises a region coding from an amino acid sequence of SEQ ID NO: 2. The repressor and operator are provided by gene transfer. The *virginiae* butanolide acts to induce the expression of a gene placed under the control of the operator sequence.

The Examiner also indicated that the specification discloses how to make and use in tobacco plant cells a gene expression inducing system, as specified above. (See Office Action, page 5, last paragraph).

Applicants amended Claim 1 to include the enabled subject matter. In view of the amendment, the rejection of Claims 1, 11, 12, 21-27 is moot. However, Applicants reserve the right to pursue the rejected claims in future prosecution.

Rejection of Claims 2-10 and 13-20 is moot in view of cancellation of these Claims.

Applicants respectfully request that the enablement rejection be withdrawn.

### **Rejection under 35 USC § 112, Second Paragraph - Indefiniteness**

The Examiner rejected Claims 1-2, 6-11, 14-17, 19-22, and 24-27 under 35 USC § 112, Second Paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention. Applicants disagree with the Examiner.

The rejection of Claims 2, 6-10, 14-17, and 19-20 is moot in view of cancellation of these Claims.

The Examiner asserted that Claim 1 is vague and indefinite for reciting "characters." More specifically, the Examiner asserted that it is unclear which "characters" of a repressor and operator would constitute a gene expression inducing system and which would not. Applicants amended Claim 1 to clarify that the method comprises providing a plant with a character of a repressor and a character of operator. The repressor and operator sequences are further defined in Claim 1.

The Examiner also asserted that Claim 1 is vague and indefinite for reciting "characters of a repressor and operator both constituting a gene expression inducing system." Specifically, the Examiner asserted that it is unclear what constitutes the gene expression inducing system and whether or not "constituting" allows for the presence of additional components in the gene expression inducing system. Applicants amended Claim 1 to clarify that the gene expression inducing system comprises the repressor, the operator, and *virginiae* butanolide as an inducer.

Claim 1 was further rejected as indefinite because the Examiner asserted that it is unclear what occurs "at the site of administration." Applicants amended Claim 1 to clarify that the expression of the gene occurs at the site of the administration of *virginiae* butanolide. The claims are read in view of the specification. As described, for example at page 13, lines 13-31, of the specification, the expression of the gene placed under the control of the operator could be satisfactorily induced.

The Examiner asserted that Claim 11 is vague and indefinite for reciting "said repressor gene," as this limitation lacks antecedent basis in Claim 1 from which Claim 11 depends. Applicants amended Claim 11 to provide the proper antecedent basis in Claim 1.

The Examiner further rejected Claim 11 as vague and indefinite for reciting "wherein a promoter for said repressor gene is a plant promoter." More specifically, the Examiner asserted that it is unclear what the promoter is for and/or what its relationship to the repressor gene is. Applicants amended Claim 11 to clarify that the "coding region of the gene coding for the repressor is connected to a site 3' downstream of a plant promoter."

The Examiner asserted that Claim 21 is indefinite for reciting "is disposed." Applicants amended Claim 21 to clarify that the operator is connected to the TATA box of the Cauliflower mosaic virus 35S promoter, as shown in SEQ ID: 4, 5, 6 and 7.

The Examiner asserted that Claim 22 is indefinite for reciting "capable of." Applicants amended Claim 22 to clarify that the gene provides the plant with fertility.

The Examiner rejected Claim 24 as indefinite in the use of parentheses. This rejection is moot in view of the amendment of Claim 24 to delete parentheses.

The Examiner asserted that Claims 25-27 are indefinite for reciting "cell transformed by the method according to Claim 1," as the method of Claim 1 does not require the transformation of cells. Applicants amended Claims 25-27 to clarify that the "cell is transformed by the gene transfer step of Claim 1."

Given the above, Applicants respectfully request that 35 U.S.C. § 112, First Paragraph rejection of Claims 1, 11, 21, 22, 24-27 be withdrawn.

### **Priority**

Applicants note that the Examiner indicated that certified copies of the priority documents have not been received in this National Stage application from the International Bureau. Applicants note that certified copies of the priority documents should be forwarded from the International Bureau to the U.S. Patent and Trademark Office.

## CONCLUSION

It should thus be seen that the invention of Claim 1 fully meets the requirements of 35 U.S.C. § 112. As such, Claim 1 and each of dependent Claims 11, 12, 21-27, and 38-42 should be allowable. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

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